REMARKS

Claims 1-9 and 39-51 were pending at the time of the Action, and Claims 10-38 and 52-54 have been canceled as being drawn to a non-elected invention.

Claims 39-42, 45 and 46 stand rejected under 35 U.S.C. § 101 as claiming the same invention as that of Claims 29-34 of prior U.S. Patent No. 6,662,045. Claims 1-9, 43 and 44 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-9, 33 and 34 of U.S. Patent No. 6,662,045. Claims 1-9 stand rejected under 35 U.S.C. § 101. Claims 1, 2 and 6-9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,800,465 to Thompson et al. ("Thompson"). Claim 47 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,630,934 to Bardy ("Bardy"). Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Thompson in view of Bardy.

Claims 43 and 47 have been canceled. Applicants submit that Claims 1-9, 39-42, 44-46, and 48-51 are in condition for allowance for at least the reasons that follow.

I. Allowable Subject Matter

Applicants acknowledge with appreciation the Examiner's statement that Claims 48-51 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 48 and 50 have been rewritten in independent form. Claims 49 and 51 depend from either Claims 48 or 50. In addition, Claim 48 has been objected to and the suggested claim amendment to Claim 48 on page 5 of the Action has been made. As such, Applicants submit that Claims 48-51 are in condition for allowance.

II. The Rejections Under 35 U.S.C. § 101

A. The Double Patenting Rejection; Claims 39-42 and 44-46

Claims 39-42, 45 and 46 stand rejected under 35 U.S.C. § 101 as claiming the same invention as that of Claims 29-34 of prior U.S. Patent No. 6,662,045. Claims 1-9, 43 and 44 stand rejected under the judicially created doctrine of obviousness-type double patenting as

being unpatentable over Claims 1-9, 33 and 34 of U.S. Patent No. 6,662,045. Claim 39 has been amended to include the recitations of Claims 43, and Claim 43 has been canceled. Therefore, Claims 39 and Claims 40-42 and 44-46 depending therefrom do not claim the same invention as U.S. Patent No. 6,662,045. Regarding the obviousness-type double patenting rejection, Applicants are submitting a Terminal Disclaimer herewith.

The Action has not cited any prior art against Claims 39-42 and 44-46, and therefore, Applicants submit that Claims 39-42 and 44-46 are in condition for allowance and request an indication of same.

B. The Non-Statutory Subject Matter Rejection; Claims 1-9

Claims 1-9 stand rejected under 35 U.S.C. § 101. The Action states that the structures claimed that are in contact with or implanted within the body is an inferential recitation of the body, which he maintains is non-statutory subject matter. Claim 1 has been amended to recite that the first atrial defibrillation electrode is "configured for positioning at the atrial septum of the heart." Applicants submit that the claims do not inferentially claim the body; however, additional claim amendments to replace "said" with "the" in certain instances have been made for clarification.

Accordingly, Applicants submit that Claims 1-9 do not inferentially claim the body, and request that the rejection under 35 U.S.C. 101 be withdrawn.

III. Claims 1-9 are patentable over Thompson and Bardy under 35 U.S.C. §§ 102 and 103

Claims 1, 2 and 6-9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Thompson. Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Thompson in view of Bardy.

A. Claim 1 is patentable over Thompson

Claim 1 recites (emphasis added):

> An implantable system for the defibrillation of the atria of a patient's heart, said system comprising:

a first catheter configured for insertion into the right atrium of said heart without extending into the right ventricle of the heart;
a first atrial defibrillation electrode carried by said catheter and configured for positioning at the atrial septum of the heart;
a second atrial defibrillation electrode which together with said first atrial defibrillation electrode provides a pair of atrial defibrillation electrodes; and
a pulse generator operatively associated with said pair of atrial defibrillation electrodes for delivering a first atrial defibrillation pulse.

Applicants submit that at least the underlined recitations of Claim 1 are not disclosed by Thompson. The Action cites column 10 and the description of **Figure 3a** of Thompson as allegedly disclosing the recitations of Claims 1, 2 and 6-9. **Figure 3a** and column 10 of Thompson discusses a pacemaker or stimulator **45** that includes multiple generators **1,2,3,4,5,** for generating component composite steering pulses for pacing the left atrium, the right atrium or the right ventricle. *See* col. 10, lines 39-43. Column 10 of Thompson further discusses leads **30** and **36**, which carry electrodes **31, 32, 33, 37, 38, 39, 41, 42** and **43** of **Figure 3a**. However, column 10 of Thompson is silent with respect to how the leads **30, 36** and electrodes **31, 32, 33, 37, 38, 39, 41, 42** and **43** are configured for placement in the heart. Applicants submit that nothing in Thompson teaches or suggests the configuration claimed in Claim 1.

For example, **Figure 1a** of Thompson illustrates electrodes **31, 32** and **33** that are on a lead **30** that is configured for placement in the left atrium of the heart. **Figure 1b** illustrates a lead **36** (including electrodes **37, 38, 39, 41, 42** and **43**) that is sized to extend into the right ventricle of the heart. **Figure 1c** illustrates a lead **36** and electrodes **38** and **39** in the right ventricle and another lead **30** with electrodes **24, 32, 33, 140, 141** and **142** in the coronary sinus vein. *See* Thompson, col. 8, lines 65-67. **Figure 1d** illustrates a lead **30** (with electrodes **31, 32** and **33**) in the coronary sinus vein and a lead **36** (with electrodes **37, 38, 39, 41, 42**and **43** positioned in the right atrium and right ventricle. *See* Thompson, col. 9, lines 28-32.

In addition, the leads shown in **Figures 1a-1d** of Thompson are not sized or configured to be positioned at the atrial septum. For example, the lead **30** and the electrodes **31, 32, 33** of **Figure 1a** of Thompson are sized so that the portion of the lead **30** carrying the

electrodes **31, 32, 33** is positioned in the coronary sinus vein. The length of the lead **30** and the position of the electrodes **31, 32, 33** are such that the electrodes **31, 32, 33** are not positioned at the atrial septum as recited in Claim 1. Accordingly, none of the other leads and electrodes discussed in Thompson are configured to be positioned at the atrial septum.

Therefore, none of the electrode configurations of Thompson teach or suggest a catheter configured for insertion into the right atrium without extending into the right ventricle and an atrial defibrillation electrode carried by the catheter and configured for positioning at the atrial septum of the heart. However, if the rejection under § 102(b) is maintained in a subsequent Action, it is respectfully requested that the specific electrode/catheter configuration relied on be pointed out.

In light of the reasons discussed above, Applicants request that the rejection of Claim 1 under § 102(b) be withdrawn. Claims 2-9 depend from Claim 1 and are patentable based on the patentability of Claim 1. In addition, certain dependent claims are separately patentable for at least the following reasons.

B. Claim 2 is separately patentable over Thompson

Claim 2 depends from Claim 1 and is patentable for the reasons discussed above. In addition, Claim 2 is patentable over Thompson for the reasons that follow.

Claim 2 recites that "said electrode is configured to be positioned within a trans-septal puncture in the atrial septum." The Action states with respect to Claim 2 that "any lead could be considered as 'configured' to be within a puncture of the septum."

Applicants respectfully disagree. As discussed with respect to Claim 1 above, none of the configurations in Thompson are configured such that an electrode is configured for positioning at the atrial septum of the heart. Applicants also disagree that any lead could be "configured" to be positioned within a trans-septal puncture in the atrial septum as maintained in the Action. The leads shown in **Figures 1a-1d** of Thompson are not sized or configured to be positioned within a trans-septal puncture. For example, the lead **30** and the electrodes **31, 32, 33** of **Figure 1a** of Thompson are sized so that the portion of the lead **30** carrying the electrodes **31, 32, 33** is positioned in the coronary sinus vein. The length of the lead **30** and the position of the electrodes **31, 32, 33** is such that the electrodes **31, 32, 33** are not

positioned at the atrial septum as recited in Claim 1 or within a trans-septal puncture in the atrial septum as recited in Claim 2. None of the other leads and electrodes discussed in Thompson are configured to be positioned within a trans-septal puncture.

In addition, Thompson teaches away from positioning an electrode within a trans-septal puncture in the atrial septum. Thompson discusses a need for "a system that provides the maximum flexibility and control without employing multiple leads having anchored electrodes at each specific site of interest." *See* Thompson, col. 3, lines 4-7. Thompson proposes a system in which pulses are steered even though a lead shifts position in or near the heart. *See* Thompson, col. 4, lines 42-44. Thompson further discusses that cardiac muscle tissue "must be stimulated without having an array of electrodes positioned substantially adjacent to the various stimulus target locations." *See* Thompson, col. 4, lines 65-67.

Accordingly, Applicants submit that Claim 2 is separately patentable for at least the above reasons and respectfully request that the rejection of Claim 2 under § 102 be withdrawn.

C. Claims 3-5 are separately patentable over Thompson and Bardy

Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Thompson in view of Bardy. Claims 3-5 depend from Claim 1 and are patentable for the reasons discussed above. In addition, Claims 3-5 are separately patentable over Thomspon and Bardy for at least the following reasons.

Claim 3 recites that "said first catheter has a distal end portion and a terminal screw connected to said distal end portion, whereby said first electrode may be fixed to the atrial septum with said terminal screw." Claim 4 recites that "said first catheter has a distal end portion and a retractable hook connected to said distal end portion, whereby said first electrode may be fixed to the atrial septum with said hook." Claim 5 recites that "said first catheter has a distal end portion and an expandable member connected to said distal end portion with said first electrode connected to said expandable member."

With respect to Claim 3, the Action concedes that Thompson does not disclose a screw-in anchor for securing the the atrial electrode within the atrium or to the septum. However, the Action takes the position that a screw-in anchor is taught by Bardy, and that it

would have been obvious to incorporate a lead anchor as taught by Bardy into the Thompson atrial lead "in order to effect improved contact." *See* the Action, page 5. With respect to Claims 4-5, the Action states that other anchoring mechanisms are "a mere choice in engineering design."

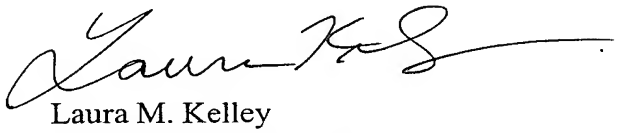
Applicants submit that there is no motivation to combine Thompson with Bardy because Thompson teaches away from using an anchoring system. As discussed above with respect to Claim 2, Thompson a need to provide flexibility and control without employing multiple leads having anchored electrodes at each specific site of interest." *See* Thompson, col. 3, lines 4-7. The leads in Thompson are allowed to shift position in or near the heart, (*see* Thompson., col. 4, lines 42-44), and cardiac muscle tissue in Thompson is stimulated "without having an array of electrodes positioned substantially adjacent to the various stimulus target locations." *See* Thompson, col. 4, lines 65-67.

Therefore, Claims 3-5 are separately patentable for at least the above reasons, and Applicants request that the rejection of Claims 3-5 under § 103 be withdrawn.

IV. Conclusion

In view of the foregoing amendment and remarks, the Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course.

Respectfully submitted,



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